IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC.,	)	
	)	C.A. No. 19-78 (RGA)
Plaintiffs,	)	CONSOLIDATED
v.	)	*Related to*:
	)	C.A. Nos. 19-103 and 19-105 (RGA)
AUROBINDO PHARMA LIMITED, et al.,	)	Defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.
Defendants.	)	

NOTICE OF DEPOSITION UNDER FRCP 30(b)(6) TO DEFENDANTS AUROBINDO PHARMA LIMITED AND AUROBINDO PHARMA USA, INC.

Pursuant to the Federal Rule of Civil Procedure 30(b)(6), this Notice is for the deposition of Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively referred to herein as "Defendants" or "Aurobindo"). Defendants are requested, at least ten (10) days prior to the deposition, to designate in writing the person(s) who will be produced and the subject matter categories upon which such person(s) will testify. The deposition will take place on a date and time to be agreed upon by the parties, and will be held stenographically and/or by video. The deposition will be videotaped and will be taken before a court reporter authorized to administer oaths for use in the above-referenced consolidated litigation as provided in the Federal Rules of Civil Procedure.

PLEASE TAKE FURTHER NOTICE that the matters on which examination is requested are the matters listed in Schedule A attached hereto and that Defendants shall produce their officer(s), director(s), managing agent(s), member(s), employee(s) or other person(s) who consents to testify, and is most knowledgeable about such matters, to testify on Defendants' behalf at said examination.

MORRIS NICHOLS ARSHT & TUNNELL LLP

/s/ Cameron P. Clark

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October 1, 2020

SCHEDULE A

DEFINITIONS

The following definitions are applicable to terms employed in this Notice of Deposition:

A. "Document" shall have the broadest meaning possible under the Federal Rules of Civil Procedure and shall include, but not be limited to, the original (or a copy when the original is not available), each non-identical copy (including those which are non-identical by reason of notations or markings, or by appearing in the files of a separate person), and any books, notebooks, pamphlets, periodicals, letters, reports, memoranda, handwritten notes, notations, messages, telegrams, wires, cables, press or news wire releases, records, studies, analyses, summaries, magazines, booklets, circulars, labels, catalogs, bulletins, instructions, operating or maintenance manuals, operating or product specifications, fabrication sheets, calendars, day-timers, notes or records of meetings, notices, purchase orders, bills, ledgers, checks, tabulations, questionnaires, surveys, drawings, sketches, schematics, blueprints, flow sheets, working papers, charts, graphs, indices, tapes, agreements, releases, appraisals, valuations, estimates, opinions, financial statements, accounting records, income statements, photographs, films or videotapes, tapes, minutes, contracts, leases, invoices, records of purchase or sale, correspondence, electronic or other transcription or taping of or notes pertaining to telephone or personal conversations or conferences, tape recordings, electromagnetic recordings, voice mail messages or transcriptions thereof, interoffice and intraoffice communications of all types, E-mail messages or printouts thereof, microfilms, CD ROMs, videotapes or cassettes, films, movies, computer printouts and all other written, printed, typed, punched, engraved, taped, filmed, recorded (electronically or otherwise), labeled, or graphic matter or thing, of whatever description, however produced or

reproduced (including computer-stored or generated data, together with instructions or programs necessary to search and retrieve such data), and shall include all attachments to (including tangible things) and enclosures with (including tangible things) any requested item, to which they are attached or with which they are enclosed, and each draft thereof.

B. "Thing" shall mean any tangible object, other than a document, and includes objects of every kind and nature including, but not limited to, prototypes, models, samples, and specimens.

C. "Communication" means the transmittal of information, whether orally, in writing, electronic, or otherwise, and whether in the form of facts, ideas, inquiries, opinions, or otherwise and includes by way of example but not limitation all discussions, conversations, interviews, negotiations, facsimiles, cablegrams, mailgrams, telegrams, telexes, cables or other forms of written or verbal interchange, however transmitted, including reports, notes, memoranda, lists, agenda, and other documents and records of communication.

D. "Person" or "Persons" shall mean an individual, corporation, proprietorship, partnership, association, joint venture, or any other entity.

E. The terms "Aurobindo" and "Defendants" shall mean Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., shall include (a) any divisions, departments, parents, sisters, subsidiaries, other organizational or operational units, and agents of Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.; (b) all predecessor or successor companies or corporations; (c) all companies, corporations, partnerships, associations, corporate affiliates, or other business entities which are or have been under the common ownership or control, in any manner, of Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., (domestic or foreign);

and (d) each of the present and former officers, directors, employees, agents, attorneys, or other representatives of any of them.

F. "Abbreviated New Drug Application" and "ANDA" refer to an Abbreviated New Drug Application filed with the Food and Drug Administration ("FDA").

G. "ANDA No. 212597" refers to ANDA No. 212597, for pirfenidone capsules, including all amendments or supplements thereto as may have been made to date or that may be made in the future.

H. "ANDA No. 212596" refers to ANDA No. 212596, for pirfenidone tablets, including all amendments or supplements thereto as may have been made to date or that may be made in the future.

I. A document or communication "relating to," "related to," "referring to," or "concerning" a given subject, means all documents or communications that constitute, contain, embody, comprise, reflect, identify, state, refer to, deal with, comment on, mention, respond to, describe, involve, or are in any way pertinent to that subject, including, but not limited to, documents concerning the presentation of other documents.

J. The masculine form of a noun or pronoun shall embrace, and shall be read and applied as the feminine or neuter, as the particular context makes appropriate and vice versa.

K. The terms "any" or "each" should be understood to include and encompass "all"; the term "or" should be understood to include and encompass "and"; and the term "and" should be understood to include and encompass "or".

L. The use of the singular form of any word includes the plural and vice versa.

M. The use of a verb in any tense shall be construed as the use of the verb in all other tenses.

N. For purposes of this Notice of Deposition, terms not specifically defined shall be given their ordinary meaning. Should Aurobindo be unable to understand the meaning of any term, Aurobindo is invited to immediately seek its clarification through Plaintiffs' counsel.

O. The " '729 patent" refers to U.S. Patent 7,566,729, entitled "Modifying Pirfenidone Treatment for Patients with Atypical Liver Function."

P. The " '236 patent" refers to U.S. Patent 7,696,236, entitled "Method of Providing Pirfenidone Therapy to a Patient."

Q. The " '707 patent" refers to U.S. Patent 7,635,707, entitled "Modifying Pirfenidone Treatment for Patients with Atypical Liver Function."

R. The " '700 patent" refers to U.S. Patent 7,767,700, entitled "Method of Providing Pirfenidone Therapy to a Patient."

S. The " '383 patent" refers to U.S. Patent 7,816,383, entitled "Methods of Administering Pirfenidone Therapy."

T. The " '610 patent" refers to U.S. Patent 7,910,610, entitled "Methods of Administering Pirfenidone Therapy."

U. The " '002 patent" refers to U.S. Patent 8,013,002, entitled "Methods of Administering Pirfenidone Therapy."

V. The " '780 patent" refers to U.S. Patent 8,318,780, entitled "Methods of Administering Pirfenidone Therapy."

W. The " '674 patent" refers to U.S. Patent 8,420,674, entitled "Method of Providing Pirfenidone Therapy to a Patient."

X. The " '462 patent" refers to U.S. Patent 8,592,462, entitled "Pirfenidone Treatment for Patients with Atypical Liver Function."

Y. The " '701 patent" refers to U.S. Patent 8,609,701, entitled "Pirfenidone Treatment for Patients with Atypical Liver Function."

Z. The " '947 patent" refers to U.S. Patent 8,778,947, entitled "Methods of Administering Pirfenidone Therapy."

AA. The "InterMune Patents" refer to the '729 patent, '236 patent, '707 patent, '700 patent, '383 patent, '610 patent, '002 patent, '780 patent, '674 patent, '462 patent, '701 patent, and '947 patent collectively.

SUBJECT MATTER CATEGORIES

1. The status of Aurobindo's ANDA Nos. 212596 and 212597, including communications (written, oral or otherwise) with the FDA (whether by Aurobindo or any of its agents) regarding approval (or projected timetable of approval) of Aurobindo's ANDA Nos. 212596 and 212597.

2. Any and all plans to transfer, change or move the manufacturing site for Aurobindo's pirfenidone product(s).

3. Aurobindo's decision to seek FDA approval to market a generic pirfenidone drug product(s) and all persons and entities who have been or will be involved in the same.

4. The contents of ANDA Nos. 212596 and 212597 and communications with the FDA concerning ANDA Nos. 212596 and 212597.

5. The drafting, creating, preparing, review, approval and filing of ANDA Nos. 212596 and 212597 and all communications with the FDA concerning ANDA Nos. 212596 and 212597.

6. The persons and entities who have been or will be involved in the drafting, creating, preparing, review, approval, and filing of ANDA Nos. 212596 and 212597, and all communications with the FDA concerning ANDA Nos. 212596 and 212597.

7. The respective roles of Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. regarding the drafting, creating, preparing, review, approval and filing of ANDA Nos. 212596 and 212597 and all communications with the FDA concerning ANDA Nos. 212596 and 212597.

8. The contents of information used for ANDA Nos. 212596 and 212597 and/or communication to the FDA concerning ANDA Nos. 212596 and 212597.

9. The drafting, creating, preparing, or supplying of information used for ANDA Nos.

212596 and 212597 and/or communication to the FDA concerning ANDA Nos. 212596 and 212597, the persons and entities who have been or will be involved in the same, and the respective roles of Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. regarding the same.

10. All FDA Warning or Deficiency Letters for Aurobindo's ANDA Nos. 212596 and 212597, and Aurobindo's efforts to comply with all FDA Warning or Deficiency Letters for Aurobindo's ANDA Nos. 212596 and 212597.

11. Aurobindo's document and email filing system(s) for documents and emails relating to ANDA Nos. 212596 and 212597, FDA Warning or Deficiency Letters, and all communications with the FDA relating to ANDA Nos. 212596 and 212597.

12. The corporate relationship between Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.

13. The proposed labeling and packaging of the generic drug products defined in ANDA Nos. 212596 and 212597, including the drafting, approval, review, and filing of the same, and all persons and entities who have been or will be involved in the same.

14. Communications with the FDA concerning proposed labeling and packaging of the generic drug products defined in ANDA Nos. 212596 and 212597, including the drafting, approval, review, and filing of the same, and all persons and entities who have been or will be involved in the same.

15. The development of the generic pirfenidone drug products that are the subject of ANDA Nos. 212596 and 212597, and all persons and entities who have been or will be involved in the same.

16. Any patent certifications in ANDA Nos. 212596 and/or 212597 with respect to one or more of the InterMune patents and any revisions, edits, amendments, and/or changes thereto as

well as all persons and entities who have been or will be involved in the same.

17. Aurobindo's decision to make any patent certifications in ANDA Nos. 212596 and/or 212597 with respect to one or more of the InterMune Patents and any revisions, edits, amendments, and/or changes thereto as well as all persons and entities who have been or will be involved in the same.

18. Aurobindo's patent certifications in ANDA Nos. 212596 and/or 212597 as to each of the InterMune Patents and any revisions, edits, amendments, and/or changes thereto as well as the making and maintaining the same and all persons and entities who have been or will be involved in the same.

19. The expected roles of Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. in the making, using, developing, selling, offering for sale, promoting, distributing or importation into the United States of the generic drug products defined in ANDA Nos. 212596 and 212597.

20. The making, using, developing, selling, offering for sale, promoting, distributing or importation into the United States of the generic drug product defined in ANDA Nos. 212596 and 212597 and all persons and entities who have been or will be involved, directly or indirectly, in the same.

21. All offers for sale, and any communications and inquiries concerning any possible sale or possible offer for sale, or request for any possible sale or possible offer for sale, of the generic drug products defined in ANDA Nos. 212596 and 212597, and the identity(s) of any individual(s) associated with such communications, inquiries, and requests.

22. All plans to distribute or promote the generic drug product defined in ANDA Nos. 212596 and 212597, including all communications relating to the availability to purchase the

generic drug products defined in ANDA Nos. 212596 and 212597 by any person or entity (including formularies).

23. All labeling, prescribing information, and packaging currently proposed in ANDA Nos. 212596 and 212597.

24. Any contemplated, anticipated or planned changes to the labeling, prescribing information and/or packaging currently proposed in ANDA Nos. 212596 and 212597.

25. The development and preparation of the proposed labeling, prescribing information, and packaging for the proposed generic pirfenidone drug products described in ANDA Nos. 212596 and 212597, including, but not limited to, any edits, amendments, revisions, or changes thereto and prior versions or drafts thereof.

26. Any labeling, prescribing information, and/or packaging or contemplated, labeling, prescribing information for the proposed generic pirfenidone drug products described in ANDA Nos. 212596 and 212597 and any revisions, edits, amendments, and/or changes thereto, including, but not limited to, any prior versions or drafts, whether or not submitted to the FDA.

27. Any steps taken or that are expected to be taken to develop an alternative or amended label, that is different from Plaintiffs' approved and current Esbriet® label, for the generic pirfenidone drug products that are the subject of ANDA Nos. 212596 and 212597, and the identity(s) of any individual(s) associated with such actions.

28. All bioequivalence testing that has been submitted to the FDA in connection with ANDA Nos. 212596 and 212597.

29. Aurobindo's projected or anticipated sales and market share forecasts for Aurobindo's proposed generic pirfenidone drug products that are the subject of ANDA Nos. 212596 and 212597, including projected or anticipated sales and/or market share for Aurobindo's

proposed generic pirfenidone drug products, and the efforts that Aurobindo and any other entity(s) will take in connection with such projected or anticipated sales and market share forecasts.

30. The methods for which Aurobindo expects or believes that its proposed generic pirfenidone drug products that are the subject of ANDA Nos. 212596 and 212597 would or will be used, including, but not limited to, any methods for treating idiopathic pulmonary fibrosis.

31. Liver enzyme elevations, hepatic abnormalities, and other side effects during pirfendione treatment and management of the same.

32. Interactions of pirfenidone with other drugs and patient and physician management of the same.

CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on October 1, 2020, upon the following in the manner indicated:

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